UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Erioglaucine [AQUASHADE]---Tox. Data Submitted Under MRID #46599 and 58032 (DUPLICATES)

ID #110301-033068

Chemical: 110301 (007A)
RD Record: S-456447
HED Project: D198329

FROM: Irving Mauer, Ph.D., Geneticist
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Health Effects Division (7509C)

03-16-94

TO: Kathryn Davis/Bonnie Adler PM #52
Reregistration Branch
Special Review and Reregistration Division (7508W)

THRU: Karl P. Baetcke, Ph.D., Chief
Toxicology Branch-I
Health Effects Division (7509C)

Registrant: AQUASHADE, Inc.

Request: Review and evaluate the following two acute toxicity studies, submitted under duplicate MRID's (47599 and 58032), both performed by Kenneth J. Kohlhof, Katonah, NY and reported out August 31, 1973:

(1) Draize Eye Irritation Study (with AQUASHADE Liquid).

(2) Acute Dermal Toxicity Study (with AQUASHADE Powder).

TB CONCLUSIONS: Both assays are provisionally ACCEPTABLE, requiring only submission of the purity of the test formulations employed (see detailed review, attached):

(1) Primary Eye Irritation (GDLN 81-4):
PII = 0 (non-irritating)

(2) Acute Dermal Toxicity (GDLN 81-2):
LD_{50} > 2000 mg/kg

ATTACHMENT: DER

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Reviewed by: Irving Mauer, Ph.D., Geneticist
Toxicology Branch-I, HED (7509C)
Secondary Reviewer: Karl P. Baetcke, Ph.D., Chief
Toxicology Branch-I, HED (7509C)

04-05-94

DATA EVALUATION RECORD

MRID No.: 00046599/00058032 (duplicates)
PC No.: 110301
RD Record No.: S456447
EPA ID No.: 110301-033068
Tox Chem. No.: 007A
Project No.: D198329

I. SUMMARY

STUDY TYPE: (81-2/81-4) Acute dermal LD_{50}/Primary eye irritation--rabbit

CHEMICAL: Erioglaucine

SYNONYMS: AQUASHADE

SPONSOR: AQUASHADE, Inc.,

TESTING FACILITY: Kenneth J. Kohlhof Inc., Katonah, NY

TITLE OF REPORT: (81-2) Acute Dermal Toxicity Study (AQUASHADE Powder)
(81-4) Draize Eye Irritation Study (AQUASHADE Liquid)

AUTHOR(S): Kenneth J. Kohlhof

STUDY NUMBER: 73-08-62

DATE ISSUED: August 31, 1973

CONCLUSIONS: Test material of unstated purity was applied to abraded/intact skin sites, or instilled into (ocular) conjunctival sacs of rabbits. No clinical toxicity was observed following either procedure:

Acute dermal LD_{50} > 2000 mg/kg
Primary irritation index (PII)=0

TB-I EVALUATION: Although these older studies were not conducted according to current FIFRA Test Guidelines (e.g., the purity of the test article was not given), the non-toxic result presented may be provisionally ACCEPTABLE, with the submission of these minor deficiencies.

II. DETAILED REVIEW

A. TEST MATERIAL: AQUASHADE

Description:	Powdered Dye/Liquid
Batches (Lots):	[Not provided]
Purity (%):	[Not provided]
Solvent/carrier/diluent:	Water

B. TEST ORGANISM: *Lagomorph*

Species:	Rabbit
Strain:	"Albino"
Age:	[Not stated]
Weights - males:/females:	2.29-2.82 kg
Source:	[Not provided]

C. STUDY DESIGN (PROTOCOL): This study was designed to assess the acute dermal potential of the test article when administered to rabbits, according to procedures outlined in regulations of the Federal Hazardous Substances Labeling Act (FHSLA).

A Statement of Quality Assurance measures (inspections/audits) was not provided.

A Statement of adherence to Good Laboratory Practice (GLP) was not provided.

D. PROCEDURES/METHODS OF ANALYSIS: (81-2): One-half of the clipped trunks (10% of body surface) of six animals (three males: three females) was abraded (the other side left intact), then the trunks enclosed in clear polyethylene sheets, taped to prevent leakage. Test substance (2g/Kg) was then injected under this bandage. After 24 hours exposure, sleeves and excess test material were removed, and animals observed for two weeks.

(81-4): 0.1 Millimeter of product (neat, as received) was instilled into the conjunctival sac of six rabbits (three males: three females); all treated eyes remained unwashed. Evaluation of ocular irritation was made one, 24, and up to 7 days later, according to the Draize Scale for scoring ocular lesions in cornea, iris, and conjunctivae. Two percent Fluorescein was applied at least once during the experimental period, to confirm the presence of any degree of irritation.

E. RESULTS:

(81-2): All animals survived the 14-day observation period, with no reported clinical effects (edema, diarrhea, et al.) or body weight changes.

Hence, the investigator concluded the test material was non-toxic to male and female rabbits.

(81-4): ^No ocular irritation was observed in any treated animal eyes up to seven days' period of observation. Hence, the PII=0.

F. TB EVALUATION: Although these older studies were not conducted according to current FIFRA Test Guidelines, they are provisionally ACCEPTABLE as satisfying the data requirements, with the submission of such required information as the purity (% a.i.) of the test article.

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